



GAS PRESSURE LEAK TESTER

MODEL GPL-5020

- Modular design, up to 20 test ports
- Auto-calibration & Rapid test sequence
- Air activated Touhy-Borst ports or Luer ports
- Stores up to 100 programmable sequences
- Leak test in less than 4 seconds
- 2 Leak rate, compliance and flow resistance testing



GENERAL FEATURES

The Gas Pressure Leak Tester, Model GPL-5020, is designed for rapid, non-destructive testing of catheters. Its modular construction allows for expanding the number of test ports from one to twenty, in multiples of five. Each test port is fitted with a small isolation solenoid valve, allowing each catheter to be tested independently. The system can also perform vacuum leak testing of catheter/stent assemblies to verify the integrity of a balloon after stent crimping. The electronic tester and modular 5 station manifolds are mounted on a pole stand with a castor base (figure 1). The unit occupies minimal floor space and can be easily moved around a clean room.

OPERATION

To accommodate leak testing of either finished catheters or semi-finished subassemblies, the ports can be configured as male luers or pneumatically activated Touhy-Borst fittings. The system uses dry nitrogen as pressure medium to test up to 500 psi. A high-speed pressure controller generates the pressure level required by the test protocol. Each manifold module includes an accuracy pressure transducer (0.5% full scale, 0.2% relative) to provide a feedback signal. A miniature pump, which is a component of each module, generates 660 mm Hg vacuum to allow for leak testing of catheter/stent assemblies. The data acquisition system then rapidly collects

pressure change information as it happens for each individual catheter. By mapping the slope of the pressure decay curve, a quick determination can be made as to the effect of the pressure loss. The loss can be attributed to gas cooling only or gas cooling plus an additional catheter leak. This approach eliminates the long waiting time (20 to 30 seconds) for the test pressure to subside. Typical test time for a leak test with our system is 4.0 seconds per catheter

TEST SET-UP

Based on your product test requirements, the operator can either select one of the pre-programmed test protocols stored in memory or create a custom protocol. Next the operator inputs test limits or acceptance criteria applicable for the chosen test protocol such as leak rate. The operator then connects the catheters to the test ports located on the bottom face of the manifold assembly (figure 4). The

catheters are thus hanging freely from the test port. This makes attachment and removal of the devices from the test manifold fast and easy without tangling. The 5-station manifold modules swivel 90 degrees about their horizontal axis, so the air chuck collets can be easily accessed.

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TEST PROCEDURE

After all the test ports are populated with catheters, the operator starts the test. The machine isolates all the test ports but one, performs the measurements and moves to the next test port. Thus each catheter is tested individually, without interference from devices connected to the other ports. The results are then transferred to a printer via a RS-232 output signal port. A red LED lamp above the test port lights up while the test is in progress and it turns off upon completion. When a particular catheter fails to meet preset acceptance criteria, the red LED lamp above the port flashes, signaling the operator to disconnect the catheter and move it to the reject bin. Thus, the operator can continue connecting new catheters and disconnecting the ones that were already tested while the testing continues.



FIGURE 3

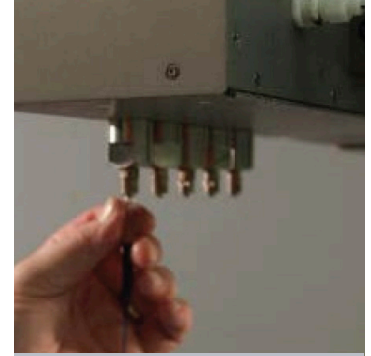


FIGURE 4

TECHNICAL SPECIFICATION

GPL-5020

Power Requirements	<p>Electrical: 100/110/220/240 VAC, 50-60Hz 120W plus 20W per manifold module</p> <p>Test Media: Dry nitrogen @ 525psi (3.5 MPa)</p> <p>Shop Air: Dry filtered Air @ 100-150psi (0.7-1.0MPa)</p>
Size	67"H X 31"W X 31"D (170cmH X 79cmW X 79cmD)
Weight	Complete system with stand and two mani-fold modules: 56lbs (25.5kg), each additional module: 9.0lbs (4.1kg)
Pressure Accuracy	± 0.5% of full scale
Pressure Resolution	0.03psi (68.9Pa)
Maximum Test Pressure	500psi (3.5MPa)
Maximum Vacuum Level	26" Hg (660 mm Hg)
Leak Rate Sensitivity	0.300 psi/min *
Capacity	1 to 20 test ports (5 test ports per manifold module)
Serial Port	9-Pin, PC compatible
Parallel Printer Port	PC compatible

* Leak rate based on standard temperature and pressure (OC, 1atm) during a four second test cycle.



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